IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
Dallas Division

INMAR RX SOLUTIONS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	No. 3:23-cv-2883-E
	)	
MERRICK B. GARLAND *et al.*,	)	
	)	
Defendants.	)	
	)	

EXHIBIT A

Order to Show Cause

U.S. Department of Justice
Drug Enforcement Administration

www.dea.gov Springfield, Virginia 22152

IN THE MATTER OF

Inmar RX Solutions, Inc.
3845 Grand Lakes Way, Suite 125
Grand Prairie, Texas 75050

Mailing Address:
1 W. 4th Street
Winston Salem, North Carolina 27101-3972

ORDER TO SHOW CAUSE

PURSUANT to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

NOTICE is hereby given to afford Inmar RX Solutions, Inc. (Inmar or Respondent) an opportunity to Show Cause before the Drug Enforcement Administration (DEA), at the DEA Hearing Facility, 700 Army Navy Drive, 2nd Floor, Arlington, Virginia, 22202, or a location designated by the Administrative Law Judge, on December 19, 2023, or on such a subsequent date designated by the Administrative Law Judge (if Respondent requests such a hearing), as to why DEA should not revoke Respondent's DEA Certificate of Registration (COR) No. RR0191902, and deny any pending application for renewal or modification of such registration, or for additional DEA registrations, pursuant to 21 U.S.C. § 824(a)(4), because Respondent has committed acts that are inconsistent with the public interest, as that term is defined in 21 U.S.C. §§ 824(a)(4) and 823(g)(1).

As detailed below, this order states DEA's basis to revoke the above-referenced DEA registration, including a ***non-exhaustive summary*** of the matters of fact and law at issue, as well as citations to laws and regulations that Respondent has violated (*see* 21 C.F.R. §§ 1301.36(e) and 1301.37(c), which DEA construes *in pari materia*). In order to preserve Respondent's rights in this proceeding, Respondent may appear in these revocation proceedings by filing a notice of appearance or request for hearing, and file an answer in the manner prescribed by regulations within 30 days from the receipt of this Order. On or before the date of your appearance, you may submit a corrective action plan that will be considered by DEA in accordance with 21 U.S.C. § 824(c).

BACKGROUND

1. Respondent is currently registered with DEA as a reverse distributor in Schedules I through V under DEA Certificate of Registration (COR) No. RR0191902 at 3845 Grand Lakes Way, Suite 125, Grand Prairie, Texas 75050. This COR expires by its own terms on November 30, 2023.

2. Respondent is licensed by the Texas Department of State Health Services as a prescription drug distributor under license number 1002646. Respondent's state license expires by its own terms on December 31, 2023.

3. On January 7, 2022, Respondent entered into a Memorandum of Agreement (MOA) with DEA after an accountability audit conducted in April 2021 revealed Respondent was unable to account for quantities of of phentermine 37.5mg (a Schedule III stimulant) and morphine 4mg/ml (a Schedule II opioid).

4. As discussed in detail below, Respondent failed to comply with its obligation to maintain effective controls against the diversion of controlled substances. Respondent's violations include the persistent failure to properly report theft or significant loss, to timely destroy or promptly return controlled substances, and to maintain complete and accurate records, all in violation of 21 U.S.C. § 823(b)(1) & (f)(1). This also represents negative experience in the distribution of controlled substances, in violation of 21 U.S.C. § 823(b)(4) & (f)(4). Respondent also violated the terms of its January 7, 2022 MOA with DEA, in violation of 21 U.S.C. § 823(b)(5) & (f)(5).

FAILURE TO MAINTAIN EFFECTIVE CONTROLS AGAINST DIVERSION

Controlled substance distributors have an affirmative obligation to "provide effective controls and procedures to guard against theft and diversion of controlled substances." 21 C.F.R. § 1301.71(a). Failure to maintain such effective controls can render a distributor's continued registration "inconsistent with the public interest" as defined in the Controlled Substances Act (CSA). *See* 21 U.S.C. § 823(b)(1) (in order for its registration to be in the public interest, a drug distributor is required to, *inter alia*, "maintain[] effective control[s] against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels");[1] *see also Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55,418, 55,473 (2015), *pet. for rev. denied Masters Pharmaceuticals, Inc. v. DEA*, 861 F.3d 206 (D.C. Cir. 2017); *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487, 36,498 (2007).

The regulations set forth a number of "security requirements" that are to be used "[i]n order to determine whether a registrant has provided effective controls against diversion." 21 C.F.R. § 1301.71(a). "In evaluating the overall security system of a registrant or applicant, the

[1] Respondent is registered with DEA as a reverse distributor in Schedules I through V. The public interest considerations for distributors in Schedules I and II are set forth at 21 U.S.C. § 823(b). The public interest considerations for distributors in Schedules III through V are set forth at 21 U.S.C. § 823(f). Insofar as these statutory provisions are materially identical, this Order cites section 823(b) for the public interest considerations for controlled substance distributors. These requirements, however, apply with equal force to Respondent's authorization to distribute controlled substances in Schedules III through V.

Administrator may consider," among other things, "[t]he adequacy of the registrant's system for monitoring the receipt, distribution, and disposition of controlled substances in its operations." *Id.* § 1301.71(b). The security requirements set forth by the regulations include a requirement to report "any theft or significant loss of any controlled substances." *Id.* § 1301.74(c).

I. Failure to Timely Destroy or Promptly Return Controlled Substances

Reverse distributors are required to either "[p]romptly deliver the controlled substance[s]" they receive "to the manufacturer or another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf," 21 C.F.R. § 1317.15(c)(2), or "[t]imely destroy the controlled substance[s]" in an authorized manner, *id.* § 1317.15(c)(3). Timeliness for destroying controlled substances is defined as "no later than 30 calendar days after receipt" of the controlled substances. *Id.* § 1317.15(d).

With respect to promptness for purposes of returns, DEA has advised that it "considered imposing specific timelines (e.g., three days, five days)" in order to "set a specific deadline that would prevent diversion and diversion opportunities." *Disposal of Controlled Substances*, 79 Fed. Reg. 53,520, 53,528 (2014). Ultimately, however, DEA determined that "violations of the flexible 'prompt' . . . standard[] would be considered under each registrant's individual circumstances." *Id*. DEA cautioned, however, that "[w]hen large volumes of pharmaceutical controlled substances accumulate, they become an attractive target for drug seekers and drug abusers." *Id.* at 53,549.

5. Respondent does not promptly deliver controlled substances received for return to the manufacturer or manufacturer's agent. Instead Respondent has a policy of "aging out" these controlled substances until they expire before returning them, in violation of 21 C.F.R. § 1317.15(c)(2). This "aging out" process takes several months and sometimes even lasts multiple years.

6. DEA analyzed Respondent's records of destructions of eight controlled substances (specifically, hydromorphone extended release 32mg (a Schedule II opioid), Dilaudid[2] 8mg (a Schedule II opioid), Adderall[3] 15mg (a Schedule II stimulant), Methadose[4] 40mg (a Schedule II opioid), morphine 4mg/ml, phentermine 15mg, ketamine 50mg/5ml (a Schedule III anesthetic), and lorazepam 40mg (a Schedule IV benzodiazepine)) that took place between January 18, 2022, and April 6, 2023. Respondent caused the destruction of approximately 49,165 batches of these controlled substances during that time period. Approximately 7,694 (approximately 15.6%) of these batches, however, were in the possession of Respondent for more than 30 days before being sent for destruction, in violation of 21 C.F.R. § 1317.15(c)(3) & (d).

7. To the extent any of the above-referenced 49,165 batches of controlled substances were not destroyed, but were instead returned to the manufacturer or another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf, thousands of these returns still would be untimely. At least 2,891 of the 49,165 batches of

[2] Dilaudid is the brand name for the controlled substance hydromorphone (a Schedule II opioid).
[3] Adderall is a brand name drug containing amphetamines (a Schedule II stimulant).
[4] Methadose is the brand name for the controlled substance methadone (a Schedule II opioid).

controlled substances were in the possession of Respondent for more than 90 days before being sent for disposal. Such disposition was not prompt, in violation of 21 C.F.R. § 1317.15(c)(2).

II. Failure to Maintain Accurate Continuing Records

"Recordkeeping is one of the CSA's principal tools for preventing the diversion of controlled substances." *Wayne Pharmacy*, 85 Fed. Reg. 63,579, 63,582 (2020). Such recordkeeping is one of the central features of the CSA's regulatory regime because "a registrant's accurate and diligent adherence to this obligation is absolutely essential to protect against the diversion of controlled substances." *Superior Pharmacy I & Superior Pharmacy II*, 81 Fed. Reg. 31,310, 31,337 (2016). Where a registrant "is abjectly unable to account for 'extraordinary quantities' of controlled substances, the Agency has held that 'it has committed acts which render its registration inconsistent with the public interest.'" *Top RX Pharmacy*, 78 Fed. Reg. 26,069, 26,084 (2013) (*quoting Ideal Pharmacy Care, Inc. d/b/a Esplande Pharmacy*, 76 Fed. Reg. 51,415, 51,416 (2011)).

Distributors must, among other things, "maintain, on a current basis, a complete and accurate record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him/her, and each inner liner, sealed inner liner, and unused and returned mail-back package[.]" 21 C.F.R. § 1304.21(a); *see also* 21 C.F.R. § 1304.22(e) (specific recordkeeping requirements for reverse distributors).

8. In April of 2023, DEA investigators conducted an audit of Respondent's controlled substances records by conducting an inventory of certain controlled substances present at Respondent's registered location and comparing that inventory to the records maintained and provided by Respondent. DEA's audit identified significant quantities of controlled substances were unaccounted for, in violation of 21 C.F.R. §§ 1304.21(a) and 1304.22(e). *See Bill Lloyd Drug*, 64 Fed. Reg. 1823, 1824 (1999) ("The shortages and overages revealed by the accountability audit show that Respondent does not keep complete and accurate records of its controlled substance handling as required by 21 U.S.C. 827 and 21 CFR 1304.21."). Specifically, Respondent was unable to account for approximately 2,730 dosage units of lorazepam 40mg (a Schedule IV benzodiazepine), and approximately 30,500 dosage units of phentermine 15mg (a Schedule III stimulant).

9. Respondent's failure to account for thousands of dosage units of controlled substances not only violated its obligation to maintain accurate records, but also its obligation to maintain effective controls against the diversion of controlled substances into illicit channels. *See, e.g.*, *Superior Pharmacy*, 81 Fed. Reg. at 31,337.

III. Failure to Properly Report Theft or Significant Loss

10. Registrants "must notify the [DEA] . . . , in writing, of any theft or significant loss of any controlled substances within one business day of discovery of the theft or loss. . . . The registrant must also complete, and submit to the Field Division Office in his or her area,

DEA Form 106 regarding the theft or loss." 21 C.F.R. § 1301.74(c)[5]. Since at least 2020, Respondent has reported tremendously high numbers of lost or stolen controlled substances to DEA. Respondent's theft and loss reports to DEA, however, have repeatedly and consistently been inaccurate.

11. The DEA Form 106, which registrants must file with DEA to report theft of significant losses, *see* 21 C.F.R. § 1301.74(c), requires registrants to report the "Number of Thefts or Losses Registrant Has Experienced in the Past 24 Months." Between January 6, 2020, and May 24, 2023, Respondent submitted over 12,000 DEA Form 106s reporting a false number of thefts of losses experienced in the past 24 months, in violation of 21 C.F.R. § 1301.74(c).

12. By failing to accurately report its prior thefts and/or losses on thousands of DEA Form 106s, Respondent violated its reporting obligations under 21 C.F.R. § 1307.74(c) and failed to comply with its obligation to maintain effective controls against the diversion of controlled substances into illicit channels. *Cf. Wayne Pharmacy*, 85 Fed. Reg. at 63,582 ("Registrant's failure to notify DEA of the significant loss of controlled substances within one business day of discovering the loss was a violation of 21 CFR 1301.76(b) and a violation of 21 CFR 1301.71, which requires all registrants to provide 'effective controls and procedures to guard against theft and diversion of controlled substances' as set forth in 1301.72-76.").

VIOLATIONS OF THE JANUARY 7, 2022 MOA

"DEA has long held that a registrant's failure to comply with the terms of a MOA can constitute acts which render his registration inconsistent with the public interest. This is so even if the violation of the MOA does not establish a violation of the CSA or its implementing regulations." *Erwin E. Feldman, D.O.*, 76 Fed. Reg. 16,835, 16,838 (2011).

13. As discussed in paragraph 3, *supra*, Respondent entered into a MOA with DEA after an accountability audit conducted in April 2021 revealed Respondent was unable to account for quantities of phentermine 37.5mg and morphine 4mg/ml. Pursuant to the terms of its January 7, 2022 MOA with DEA, Respondent was required to "conduct monthly controlled substance inventory accountability audits." January 7, 2022 MOA ¶ 8.f. These audits are conducted by selecting certain controlled substances to audit, conducting an inventory of those controlled substances present at Respondent's registered location, and comparing that inventory to records maintained by Respondent (including prior inventories, and records of drugs received and disposed of) to determine if Respondent is correctly accounting for all of its controlled substances.

[5] This statute was revised effective July 24, 2023, where 21 C.F.R. §1301.74(c) now states that "[t]he registrant must also file a complete and accurate DEA Form 106 with the Administration through the DEA Diversion Control Division secure network application within 45 calendar days after discovery of the theft or loss."

14. Respondent failed to conduct monthly controlled substance inventory accountability audits for a 16-month period, from on or about January 2022 through April 2023.

15. Specifically, from on or about January 2022 through March 2022, a period of three months, Respondent did not attempt any controlled substance inventory accountability audit.

16. The audits Respondent conducted from on or about April 2022 through April 2023, a period of 13 months, were not valid controlled substance inventory accountability audits. Pertinent details follow.

    a. Respondent relied on controlled substance inventory numbers reported by its electronic inventory system, and failed to physically count the controlled substances under audit. Thus, Respondent failed to verify these quantities.

    b. Respondent also failed to review records regarding the number of controlled substances that it had received and disposed of to determine if it was correctly accounting for the numbers of controlled substances it had on hand. Instead, Respondent simply conducted spot checks to determine if certain inventory tags were present in the places its records indicated they should be.

17. As delineated in the preceding paragraphs, Respondent violated paragraph 5 of the MOA where Respondent agreed to "abide by all federal, state, and local laws and regulations relating to controlled substances."

THE following procedures are available to Respondent in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause, Respondent may file with DEA a written request for a hearing and file an answer in the form set forth in 21 C.F.R. § 1316.47. *See* 21 C.F.R. § 1301.43(a). If Respondent fails to file such a request and answer, Respondent shall be deemed to have waived Respondent's right to a hearing and to be in default. *See* 21 C.F.R. § 1301.43(c)(1).

2. Should Respondent request a hearing and fail to timely file an answer, plead, or otherwise defend, or should Respondent request a hearing and then fail to appear at the designated hearing, Respondent shall be deemed to have waived the right to a hearing and to be in default, and DEA may enter an order terminating the proceeding. *See* 21 C.F.R. §§ 1301.43(c)(2), (c)(3), (d).

3. Default constitutes a waiver of Respondent's right to a hearing and an admission of the factual allegations of the Order to Show Cause. *See* 21 C.F.R. § 1301.43(e). In the event that Respondent is deemed in default or an order terminating the proceedings has been issued, DEA may enter a default final order pursuant to 21 C.F.R. § 1316.67. *See* 21 C.F.R. § 1301.43(f)(1).

Requests for hearing should be filed by email with the Office of Administrative Law Judges at the following address: ECF-DEA@dea.gov, with a copy simultaneously provided to the Government at the following address: DEA.Registration.Litigation@dea.gov. Except as provided below with respect to a corrective action plan, correspondence concerning this matter, including the request referenced above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152. A copy of the same shall also be served on Government Counsels, Paula M. Trahos, Darlene K. Tzou, and Beatriz Gonzalez, and be addressed to the Office of Chief Counsel, Diversion Section, 8701 Morrissette Drive, Springfield, VA 22152.

OPPORTUNITY TO SUBMIT CORRECTIVE ACTION PLAN

In addition to the option to request a hearing as set forth above, in accordance with 21 U.S.C. § 824(c)(2)(C), Respondent has the opportunity to submit a corrective action plan, which must be received by the Assistant Administrator, Diversion Control Division, on or before the date of Respondent's appearance. Respondent is not required to submit a corrective action plan, nor will any adverse inference be drawn if Respondent chooses not to do so. If Respondent wishes to submit a corrective action plan, it must be submitted directly to the Assistant Administrator, Diversion Control Division, who will decide whether, in view of the plan and the allegations set forth in this Order to Show Cause, the proceedings to revoke your registration should be discontinued, or deferred for the purposes of modification, amendment, or clarification of such plan. Any corrective action plan should be clearly labeled "Corrective Action Plan" and submitted by email to Thomas W. Prevoznik, Assistant Administrator, Diversion Control Division, at the following address: CAPresponse@usdoj.gov.

A copy of the corrective action plan shall also be served on Government Counsels, Paula M. Trahos, Darlene K. Tzou, and Beatriz Gonzalez, and be addressed to the Office of Chief Counsel, Diversion Section, 8701 Morrissette Drive, Springfield, VA 22152.

In the event Respondent submits a corrective action plan and the Assistant Administrator decides not to discontinue or postpone the proceedings, please note that such a decision is not a final determination by the agency regarding Respondent's corrective action plan or Respondent's registration. In such circumstances, the Administrator may nonetheless consider the corrective action plan in issuing the final order at the conclusion of the proceedings.

Finally, please be advised that the submission of a corrective action plan shall not constitute a request for a hearing. As indicated, if Respondent chooses to submit a corrective action plan and also wishes to proceed by requesting a hearing, Respondent must separately submit its request for a hearing in accordance with the instructions above.

_____
Thomas W. Prevoznik
Assistant Administrator
Diversion Control Division
Drug Enforcement Administration

cc: Hearing Clerk, Office of Administrative Law Judges
Paula M. Trahos, Counsel for the Government
Darlene K. Tzou, Counsel for the Government
Beatriz Gonzalez, Counsel for the Government